K042930

DEC 2 8 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	SpineVision, Inc. 3003 Summit Blvd., Suite 1400 Atlanta, GA 30319 Phone: 404-460-5077
510(K) CONTACT:	Lynnette Whitaker Vice President, Regulatory Affairs 574-269-9776
TRADE NAME:	Spacevision™ Cage System
COMMON NAME:	Vertebral Body Replacement
CLASSIFICATION: Orthosis	888.3060 Spinal Intervertebral Body Fixation
DEVICE PRODUCT CODE:	Product code: 87 MQP
SUBSTANTIALLY EQUIVALENT DEVICES:	K041888, Tetris™ Spinal Implant, Signus Medizintechnik GMBH K040928, Expandable PEEK VBR Implant, Interpore Cross International K042268, EBI CAS Spine Spacer System, EBI, L.P. K003709, Mesh Cage System, Surgical Dynamics™

DEVICE DESCRIPTION AND INTENDED USE:
The Spacevision cage implant is an oval shaped device with teeth on the upper and lower portions. The implant is hollow and can be used with bone graft when implanted. The implant is manufactured from PEEK Optima® LT1 and contains tantalum beads for location on radiographs. A variety of sizes are available, and the implants may be inserted individually or in pairs.

INDICATIONS FOR USE:
The Spacevision™ Cage System is intended for use as partial replacement (i.e. partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body in the thoracolumbar spine (T1-L5). The

Spacevision Cage System is also indicated in the treatment of trauma/fractures of the thoracic and lumbar spine.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The components of the Spacevision Cage System are identical in design, material, and intended use to other spinal instrumentation systems that have been cleared by FDA for vertebral body replacement. Mechanical testing was performed to demonstrate the equivalence of the construct design to currently marketed spinal systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 2004

Ms. Lynnette Whitaker
Vice President, Regulatory Affairs
SpineVision, Inc.
3003 Summit Boulevard, Suite 1400
Atlanta, Georgia 30319

Re: K042930
Trade/Device Name: Spacevision™ Cage System (Partial Vertebrectomy)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: October 20, 2004
Received: October 22, 2004

Dear Ms. Whitaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042930

Indications for Use

510(k) Number (if known):

Device Name: Spacevision™ Cage System

Indications For Use:

The Spacevision™ Cage System is intended for use as partial replacement (i.e. partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body in the thoracolumbar spine (T1-L5). The Spacevision Cage System is also indicated in the treatment of trauma/fractures of the thoracic and lumbar spine.

Prescription Use __x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042930